78B-4-505. Liability of reprocessor of single-use medical devices.

(1) For purposes of this section:

(a) "Critical single-use medical device" means a medical device that:

(i) is marked as a single-use device by the original manufacturer; and

(ii) is intended to directly contact normally sterile tissue or body spaces during use, or is physically connected to a device intended to contact normally sterile tissue or body spaces during use.

(b) "Original manufacturer" means any person or entity who designs, manufactures, fabricates, assembles, or processes a critical single-use medical device which is new and has not been used in a previous medical procedure.

(c) "Reprocessor" includes a person or entity who performs the functions of contract sterilization, installation, relabeling, remanufacturing, repacking, or specification development of a reprocessed critical single-use medical device.

(d) "Reconditioned or reprocessed critical single-use medical device" means a critical single use medical device that:

(i) has previously been used on a patient and has been subject to additional processing and manufacturing for the purpose of additional use on a different patient;

(ii) includes a device that meets the definition under Subsection (1)(a), but has been labeled by the reprocessor as "recycled," "refurbished," or "reused"; and

(iii) does not include a disposable or critical single-use medical device that has been opened but not used on an individual.

(2) A reprocessor who reconditions or reprocesses a critical single-use medical device assumes the liability:

(a) of the original manufacturer of the critical single-use medical device; and

(b) for the safety and effectiveness of the reconditioned or reprocessed critical single-use medical device.

Renumbered and Amended by Chapter 3, 2008 General Session